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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,295	10/31/2003	Hikmat Hojeibane	CRD-5051	2568

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/699,295	Applicant(s) HOJEIBANE ET AL.	
	Examiner Brian E Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 23, 25, 26, 30 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 24, 27-29, 32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/18/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Specie I frame, Specie A anchor, Specie 1 limiting means in the reply filed on 6/20/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 23,25,26,30, 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "*The present invention relates to*," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it should not include implied language. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claims 17-19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 17 fails to limit a previous claim since it depends from itself. Claims 18,19 depend from claim 17.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5,8,9,22,24,27-29,32,33 are rejected under 35 U.S.C. 102(e) as being anticipated by Huter et al. (6511496). Fig. 1 shows a prosthetic valve having an anchor structure on a balloon, which is attached to a catheter device that has a collar **40** proximal to the anchor. The collar is attached to a cantilever strut assembly **24** which has a membrane assembly **22** attached thereto that has a first open end and a second closed end. Huter discloses the structural frame may be made of metals or polymers, col. 4, lines 2-4. The membrane is made of synthetic material, col. 7, lines 45-49. Both the connecting member and the cantilever strut are "substantially straight". The use of

"substantially constant diameter" or "substantially conical shape" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. It can be construed that element 26 can be a centering leg.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huter et al. '496 in view of Konya et al. (6368338). Huter et al. is explained supra. However, Huter fails to disclose the membrane material comprises a reinforcement fiber. Konya shows (Fig. 1) a filtering device. Konya also teaches that the filtering device can include reinforcement or structural fibers, col. 12, lines 23-31. It would have been obvious to one of ordinary skill in the art to use reinforcement fibers as taught by Konya with the membrane of Huter such that it strengthens the apparatus and prevents collapse.

Claims 6 and 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Huter et al. '496 in view of Quijano et al. (5500014). Huter is explained supra. However, Huter does not disclose the use of biological vein material for the membrane. Quijano et al. teach that venous graft material is used in prosthetic valve devices (col. 6, lines 6,7) and that tanning the material provides certain stiffness properties, col. 11, lines 22-

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25. It would have been obvious to one of ordinary skill in the art to use venous material as taught by Quijano et al. for the membrane of Huter et al. such that it provides a natural biological material that is sufficient to withstand the pressure of the blood flow in the patient since it is a natural material.

Claims 10,12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huter et al. '496 in view of Alt et al. (5788979). Huter et al. is explained as before. However, Huter fails to disclose the structural frame or the membrane is coated with a therapeutic agent. Alt et al. teach that biodegradable polymer materials can be loaded with drugs or pharmaceutical agents (col. 4, lines 14-29) to treat an area where a prosthesis (col. 8, lines 57-60) is implanted. It would have been obvious to one of ordinary skill in the art to use a biodegradable polymer with a drug as taught by Huter et al. with the device of Alt et al. such that it prevents restenosis or thrombosis from occurring.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ishimaru (EP 1097728) discloses a stent with a delivery system having cantilever strut members.

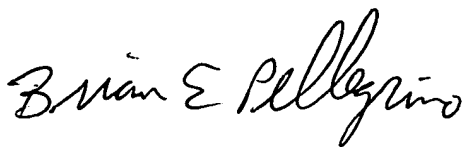
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (6:30am-4pm) and alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

A handwritten signature in black ink that reads "Brian E. Pellegrino". The signature is written in a cursive, flowing style.

BRIAN E. PELLEGRINO
PRIMARY EXAMINER